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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/019,067 | 06/28/2002 | Mats Paulsson | HLZ-001US | 7795 |
| 959 | 7590 | 02/06/2006 | EXAMINER | |
| LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109 | | | COUNTS, GARY W | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/019,067 | PAULSSON ET AL. | |
| | Examiner Gary W. Counts | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 October 2005.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 13-16 and 26-31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) _____ is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) 13-16 and 26-31 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 13-16 and the addition of claims 26-31 in the reply filed on October 28, 2005 is acknowledged.

Upon further consideration and review of applicant's amendment to the claims, the following species restriction is required.

This application contains claims directed to the following patentably distinct species of the diseases as claimed.

Applicant is required to elect a particular disease for diagnosis, selected from the following:

| | |
|--|--|
| a. dermatitis herpetiformis | r. primary biliary cirrhosis |
| b. morbus Duhring | s. primary sclerosing cholangitis |
| c. AI haemolytic anaemia | t. progressive systemic sclerosis |
| d. AI thrombocytopenic purpura | u. recurrent pericarditis |
| e. AI thyroid diseases | v. relapsing polychondritis |
| f. atrophic gastritis-pernicious anaemia | w. rheumatoid arthritis |
| g. infertility | x. rheumatism |
| h. increased risk of abortions | y. sarcoidosis |
| i. reduced fetal growth | z. Sjogren's syndrome |
| j. Crohn's disease | aa. SLE |
| k. colitis ulcerosa | bb. Splenic atrophy |
| l. Goodpasture syndrome | cc. Type I(insulin-dependent) diabetes |
| m. IgA nephropathy | dd. Diabetes mellitus |

| | |
|---------------------------|----------------------------|
| n. IgA glomerulonephritis | ee. Wegener granulomatosis |
| o. myasthenia gravis | ff. ulcerative colitis |
| p. partial lipodystrophy | gg. Vasculitis |
| q. polymyositis | hh. vitiligo |

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 is generic. Claims 14-16 and 26-31 are subject to species election.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Compliance

: The specification lists amino acids sequences which are greater than four amino acids. For example on pages 7-9 of the specification. There has been no CRF submitted or paper copy of the "Sequence listing". Further, The sequences listed in the specification should include sequence identifiers.

Appropriate correction is required.

(1) The application clearly fails to comply with the requirement of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

(2) This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

(3) A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

Applicant must provide:

An initial or substitute computer readable from (CFR) copy of the "Sequence Listing".

An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include not new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

The time for reply of the sequence compliance is set to the time of reply for the office action.

For questions regarding compliance to these requirements, please contact :

For Rules Interpretation, call (571) 272-2510

For CRF Submission Help, call (571) 272-2501/2583

Patentin Software Program Support

Technical Assistance.....703-287-0200

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Gary Counts
Examiner
Art Unit 1641
January 31, 2006

Long V. Le
LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/03/06

HOW TO SEND SEQUENCES TO USPTO

The addresses below are effective 5 June 2004. Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

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